RESPONSE

I. Status of the Claims

No claims have been cancelled. No claims have been amended. No new claims have been added.

Claims 1-5 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**.

II. Rejection of Claims 1-5 Under 35 U.S.C. § 101

The Action first rejects claims 1-5 under 35 U.S.C. § 101, as allegedly lacking a patentable utility. Applicants respectfully traverse.

Applicants pointed out in the response filed on March 3, 2003 ("the previous response") to the First Action in this case, which was issued on October 1, 2002 ("the First Action") that the present nucleic acid sequences have a substantial and specific utility in **forensic** analysis (see, for example, the specification at page 14, lines 5-8). As described in the specification on page 7, lines 21-30, the present sequences define two coding single nucleotide polymorphisms - specifically, a T/G polymorphism at position 233 of SEQ ID NO:1, which can lead to a valine or glycine residue at amino acid position 78 of SEQ ID NO:2, and a C/T polymorphism at position 316 of SEQ ID NO:1, which can lead to an arginine or cysteine residue at amino acid position 106 of SEQ ID NO:2. The Examiner questions this asserted utility because there is no "precise information about the individual from which a sample under analysis was taken" (Action at page 3). Applicants point out that this arguments has absolutely no bearing on the assertion that the polymorphisms described by Applicants can be used in **forensic** analysis. Forensic analysis merely determines the presence or absence of one or more particular polymorphic markers as a means of distinguishing between individuals. As such, forensic analysis requires absolutely no information whatsoever about "information about the individual from which a sample under analysis was taken". Thus, the Examiner's argument in no way supports the allegation that the present claims lack a patentable utility.

Importantly, the Examiner goes on to admit that "(i)t is well known in the art of molecular

biology that the nucleotide sequences encoding an amino acid sequence of any particular protein will have inconsequential differences from individual to individual, as will the amino acid sequences encoded thereby. This is why all humans are not all identical and why DNA fingerprinting works" (Action bridging pages 2 and 3). However, after this admission that the presently described polymorphic markers have utility in forensic analysis, the Examiner states that this is not a specific utility because "almost any cDNA can be employed as a forensic marker in some capacity" (Action at page 3). This argument is flawed in a **number** of respects. First, until a polymorphic marker is actually described it cannot be used in forensic analysis. Put another way, simply because there is a likelihood, even a significant likelihood, that a particular nucleic acid sequence will contain a polymorphism and thus be useful in forensic analysis, until such a polymorphism is actually identified and described, such a likelihood is **meaningless**. The Examiner appears to be attempting to use the information presented for the first time by Applicants in the instant specification as hindsight verification that the presently claimed sequence would be expected to have polymorphic markers. Such hindsight analysis based on Applicants discovery is completely improper. Second, the Examiner is clearly confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an improper standard. The relevant case law cited by Applicants in the previous response makes it abundantly clear that the presence of other or even more useful polymorphic markers for forensic analysis does **not** mean that the present sequences lack a specific utility. As **clearly** stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*"):

> An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Importantly, the holding in the *Carl Zeiss* case is **mandatory legal authority** that essentially controls the outcome of the present case. This case, and particularly the cited quote, **directly** rebuts the Examiner's argument, which is presumably why the Examiner failed to address the holding of *Carl Zeiss* in the Action. Furthermore, the requirement for a unique utility is clearly not the standard

adopted by the Patent and Trademark Office. If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, such as cancer and bacterial or viral infections, just to name a few particular examples, because examples of each of these have already been described and patented. All batteries have the exact same utility - specifically, to provide power. All automobile tires have the exact same utility - specifically, for use on automobiles. All golf balls and golf clubs have the exact same utility - specifically, use in the game of golf. All cancer treatments have the exact same utility - specifically, to treat cancer. All anti-infectious agents have the exact same broader utility - specifically, to treat infections. However, only the briefest perusal of virtually any issue of the Official Gazette provides numerous examples of patents being granted on each of the above compositions every week. Furthermore, if a composition needed to be unique to be patented, the entire class and subclass system would be an effort in futility, as the class and subclass system serves solely to group such common inventions, which would not be required if each invention needed to have a unique utility. Thus, the present sequence clearly meets the requirements of 35 U.S.C. § 101.

Instead of addressing Applicants' arguments, the Examiner merely rehashes the standard irrelevant arguments concerning general utility - "that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromotography (HPLC) and gas chromotography", and that "any item having a constant mass within an acceptable range can be employed to calibrate a produce scale in a grocery store" (Action bridging pages 3 and 4). These staid arguments are flawed in at least two critical respects. First, the quote from the Examiner used above, "**almost** any cDNA can be employed as a forensic marker in some capacity" (Action at page 3, emphasis added), points to the fact that not **all** nucleic acids have utility in forensic analysis. Thus, utility of nucleic acid sequences that contain defined polymorphic markers in forensic analysis is not a general utility. Second, the reason that such utilities as those listed by the Examiner are not specific is because these general utilities are applicable to a large number of **unrelated** compositions. Use as a calibration standard for a "produce scale" is a utility that is applicable to any composition,

no matter how unrelated, that has mass. In other words, a metal block, an automobile, an elephant, or a nucleic acid molecule containing a polymorphism could be used to calibrate a produce scale, which is why use as a calibration standard for a produce scale is not a specific utility. However, a metal block, an automobile, or an elephant cannot be used in human forensic analysis. In fact, only nucleic acids, and specifically those human nucleic acids that contain a defined polymorphic marker, can be so used. Thus, this argument also fails to support the Examiner's position.

Furthermore, as the presently described polymorphisms are part of the family of polymorphisms that have a well established utility, Applicants reliance on *In re Brana*, (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*") in the previous response is not at all "misplaced" (the Final Action at page 6). The Examiner states that reliance on *Brana* is misplaced because "(t)he protein encoded by the nucleic acid of the instant invention does not belong to a family of compounds with a common well-established and substantial utility" (Action at page 6). However, Applicants' reliance on *Brana* is based on the indisputable fact that the presently described polymorphisms are part of the family of polymorphisms that have a well established utility. Thus, the Examiner's argument completely fails to support the allegation that the present claims lack a patentable utility.

Applicants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), and thus the question of the utility of the presently claimed invention should be laid to rest. However, Applicants pointed to a number of additional utilities of the present sequence, including use in a gene chip format to provide a high throughput analysis of the level of gene expression, and in mapping the claimed sequence to human chromosome 11. The Examiner's main argument concerning these utilities is that, once again, other nucleic acid sequences can be used in a similar fashion - "almost any cDNA can be ... used as a chromosomal or tissue marker or in a gene chip for expression profiling" (Action at page 3). In addition to the detailed arguments presented by Applicants in the previous response with regard to each of these asserted utilities, Applicants once again point out that these arguments are completely rebuffed by the Federal Circuit's holding in *Carl Zeiss*, *supra* ("[A]n invention need not be the best or only way to accomplish a certain result").

Furthermore, it has been clearly established that a statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA, 1974; "*Langer*"); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971). As clearly set forth in *Langer*:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Langer at 297, emphasis in original. As set forth in the MPEP, "Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered 'false' by a person of ordinary skill in the art" (MPEP, Eighth Edition at 2100-40, emphasis added). Absent such evidence from the Examiner, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Additionally, the specification as originally filed indicates that the presently claimed sequence is involved in "chemical communication" (specification at page 1, line 28). Applicants invite the Examiner's attention to the fact that a sequence sharing 100% percent identity at the protein level over the entire length of the claimed sequence is present in the leading scientific repository for biological sequence data (GenBank), and has been annotated by third party scientists *wholly unaffiliated with Applicants* as "Homo sapiens similar to olfactory receptor MOR40-13" (GenBank accession number XM_291808; alignment shown in **Exhibit B**), and two sequences sharing nearly 100% percent identity at the protein level over the entire length of the claimed sequence are present in the leading scientific repository for biological sequence data (GenBank), and have been annotated by third party scientists *wholly unaffiliated with Applicants* as "Homo sapiens similar to olfactory receptor MOR40-13" and "Homo sapiens gene for seven transmembrane helix receptor" (GenBank accession numbers XM_062282 and AB065812; alignments shown in **Exhibit C**). Furthermore, the murine olfactory receptor sequence referred to above (MOR40-13) shares over 84% percent identity at the protein level and 91% similarity at the protein level with the claimed sequence (GenBank accession numbers NM_146312 and AY073781; alignments shown in **Exhibit D**). The legal test for utility simply involves an assessment of whether those skilled in the art would

find any of the utilities described for the invention to be credible or believable. Given these GenBank annotations, there can be no question that those skilled in the art would clearly believe that Applicants' sequence is an olfactory receptor protein, which is clearly involved in chemical communication. Thus, the present sequence clearly meets the requirements of 35 U.S.C. § 101.

Finally, as detailed in the previous response, the requirements set forth in the Action for compliance with 35 U.S.C. § 101 do not comply with the requirements set forth by the Patent and Trademark Office ("the PTO") itself for compliance with 35 U.S.C. § 101. In addition to the remarks set forth in the previous response, Applicants also point out that the Office has recently issued U.S. Patent 6,043,052, which concerns an "orphan" G-Protein coupled receptor identified based only on homology to the orphan receptor GPR25, similar to the situation with Applicants' currently claimed sequence. Importantly, this issued patent contains no examples of the "real world" utilities seemingly required in the present case. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section III, below), Applicants submit that the present polynucleotides must also meet the requirements of 35 U.S.C. § 101. While Applicants understand that "each application is examined on its own merits" (Action at page 7), Applicants are unaware of any changes to 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit, since the issuance of these patents that render the subject matter claimed in these patents, which is similar to the subject matter in question in the present application, as suddenly failing to meet the requirements of 35 U.S.C. § 101. Thus, holding Applicants to a different standard of utility would be arbitrary and capricious, and, like other clear violations of due process, cannot stand.

For each of the foregoing reasons, as well as the reasons set forth in the previous response, Applicants submit that as the presently claimed nucleic acid molecules have been shown to have a substantial, specific, credible and well-established utility, the rejection of claims 1-5 under 35 U.S.C. § 101 has been overcome, and request that the rejection be withdrawn.

III. Rejection of Claims 1-5 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1-5 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not

supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1-5 have been shown to have "a specific, substantial, and credible utility", as detailed in section II above, the present rejection of claims 1-5 under 35 U.S.C. § 112, first paragraph, cannot stand.

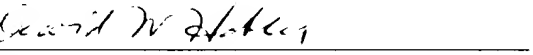
Applicants therefore request that the rejection of claims 1-5 under 35 U.S.C. § 112, first paragraph, be withdrawn.

IV. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Ulm have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

August 22 2003
Date



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